

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

Date of mailing (day/month/year) 11 January 2001 (11.01.01)	
International application No. PCT/IB00/00530	Applicant's or agent's file reference F15037 LVDW
International filing date (day/month/year) 26 April 2000 (26.04.00)	Priority date (day/month/year) 29 April 1999 (29.04.99)
Applicant LAMB, Peter, James, Brian	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
 29 November 2000 (29.11.00)

☐ in a notice effecting later election filed with the International Bureau on:  
 \_\_\_\_\_

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).



The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Olivia TEFY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>F15037 LVDW</b>		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. <b>PCT/IB00/00530</b>	International filing date (day/month/year) <b>26/04/2000</b>	Priority date (day/month/year) <b>29/04/1999</b>
International Patent Classification (IPC) or national classification and IPC <b>A61M37/00</b>		
Applicant <b>LAMB, Peter, James, Brian</b>		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 16 sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"><li>I <input checked="" type="checkbox"/> Basis of the report</li><li>II <input type="checkbox"/> Priority</li><li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li><li>IV <input checked="" type="checkbox"/> Lack of unity of invention</li><li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li><li>VI <input type="checkbox"/> Certain documents cited</li><li>VII <input checked="" type="checkbox"/> Certain defects in the international application</li><li>VIII <input type="checkbox"/> Certain observations on the international application</li></ul>		
Date of submission of the demand <b>29/11/2000</b>		Date of completion of this report <b>14.08.2001</b>
Name and mailing address of the international preliminary examining authority:  <b>European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tlx 523656 epmu d Fax +49 89 2399 - 4465</b>		Authorized officer <b>Josten, S</b> Telephone No. +49 89 2399 2338 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**International application No. **PCT/IB00/00530****I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-13 as received on 14/06/2001 with letter of 14/06/2001

**Claims, No.:**

1-17 as received on 14/06/2001 with letter of 14/06/2001

**Drawings, sheets:**

1/2,2/2 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**International application No. **PCT/IB00/00530**☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under Item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 3, 10, 14-17.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 3, 10, 14-17.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

☒ restricted the claims.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB00/00530

- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
- ☐ not complied with for the following reasons:
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1, 4-9, 11-13.

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	1, 4-9, 11-13
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1, 4-9, 11-13
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1, 4-9, 11-13
	No:	Claims	

### 2. Citations and explanations see separate sheet

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
see separate sheet

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB00/00530

**Re Item III****Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. Reference is made to the fact that it is the originally filed set of claims which forms the basis of the International Search Report. The present independent claim 3 did not form part of the originally filed set of claims. Present claim 3 was filed as a new independent claim with the applicant's letter of 14.06.01. Thus, claim 3 has not been searched by the International Search Authority. The same applies to claim 14 which also has no basis in the originally filed set of claims. Claims 10 and 15 are dependent upon unsearched independent claim 3. Claims 16 and 17 have not been searched by the International Search Authority as indicated in the International Search Report (see Box I).

**Re Item IV****Lack of unity of invention**

2. According to his letter of 23.02.01 the applicant wished the International Preliminary Examination Report to be established on the basis of originally filed claims 1, 2 and 5 to 16. These originally filed claims 1, 2 and 5 to 16 correspond with claims 1, 4 to 9 and 11 to 13 of the present set of claims. The applicant's wish to restrict the claims is also observed as the the present set of claims. No written opinion is therefore given for the present independent claim 2 which is based on originally filed independent claim 3.

**Re Item V****Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

3. The document GB-A-2033754 (=D2) is considered to represent the closest prior art. However, neither D2 nor the other documents cited in the Search Report disclose the features of present claim 1 that a portion of the passage, located in the gripping portion, is curved in the longitudinal direction of the

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB00/00530

passage. By means of these features the problem of improving the ease and comfort of use of the device is solved.

Claim 1, therefore, appears to meet the requirements of Articles 33(2) and 33(3) PCT.

4. Claims 4 to 9 and 11 to 13 are dependent upon claim 1 and each relate to preferred embodiments of the subject-matter of claim 1. Thus, claims 4 to 9 and 11 to 13 also appear to meet the requirements of Articles 33(2) and 33(3) PCT.

**Re Item VII****Certain defects in the international application**

5. The application does not meet the requirements of Rule 6.3(b) PCT since the independent claim should have been properly cast in the two-part form, with those features which in combination are known from D1 being placed in the preamble.
6. The application does not meet the requirements of Rule 6.2(b) PCT since reference signs in parentheses should have been inserted in the claims to increase their intelligibility. This applies to both the preamble and characterising portion.

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>F15037 LVDW</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/IB 00/ 00530</b>	International filing date (day/month/year) <b>26/04/2000</b>	(Earliest) Priority Date (day/month/year) <b>29/04/1999</b>
Applicant <b>LAMB, Peter, James, Brian</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of Invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☒ because this figure better characterizes the invention.

1&6

☐ None of the figures.



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 00/00530

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 7 A61M37/00 A61F13/26

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ✓	DE 522 404 C (H. E. HELLWIG) 8 April 1931 (1931-04-08) the whole document	1,10,11, 13,16
Y	---	4-7
X ✓	GB 2 033 754 A (KAO CORP) 29 May 1980 (1980-05-29) page 3, line 89 - line 106 figures 5,13,14,20	3,9,11
Y	---	4-7
A ✓	---	2,14,15
A	US 4 769 011 A (SWANIGER JAMES R) 6 September 1988 (1988-09-06) figure 1	8,11
	---	
	-/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

12 July 2000

Date of mailing of the international search report

19/07/2000

Name and mailing address of the ISA

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 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax: (+31-70) 340-3016

Authorized officer

Sedy, R

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 00/00530

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 314 464 A (EASTMAN WILLIAM J ET AL)  24 May 1994 (1994-05-24)  figure 1</p> <p>-----</p>	9

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

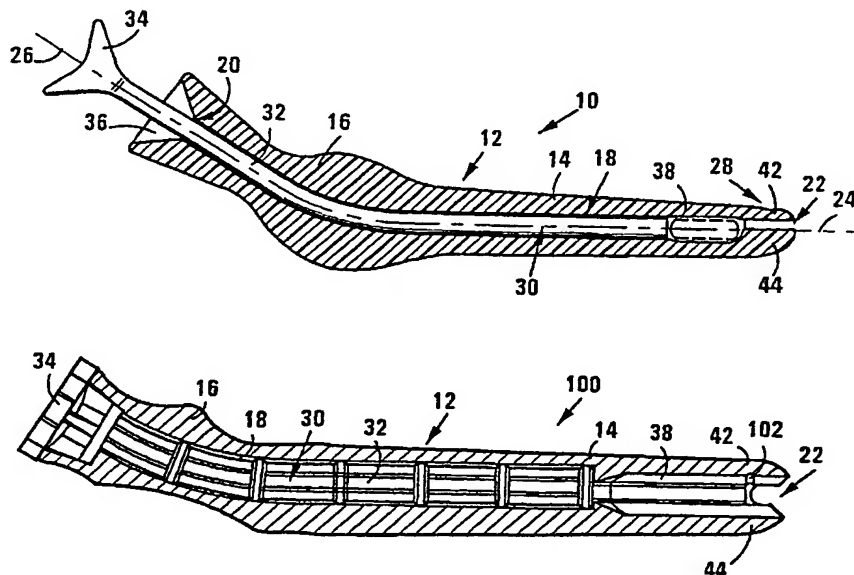
PCT/IB 00/00530

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 522404	C	NONE	
GB 2033754	A	29-05-1980	JP 55047852 A 05-04-1980
			JP 57004258 B 25-01-1982
			JP 55063644 A 13-05-1980
			JP 57004259 B 25-01-1982
			AU 5141279 A 17-04-1980
			BE 879157 A 01-02-1980
			DE 2940022 A 30-04-1980
			FR 2437827 A 30-04-1980
US 4769011	A	06-09-1988	NONE
US 5314464	A	24-05-1994	AU 672998 B 24-10-1996
			AU 4851693 A 26-04-1994
			CA 2144526 A 14-04-1994
			DE 69328256 D 04-05-2000
			EP 0662799 A 19-07-1995
			JP 2703115 B 26-01-1998
			JP 8500755 T 30-01-1996
			WO 9407405 A 14-04-1994

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>7</sup> : <b>A61M 37/00, A61F 13/26</b>	<b>A1</b>	(11) International Publication Number: <b>WO 00/66213</b> (43) International Publication Date: 9 November 2000 (09.11.00)
<p>(21) International Application Number: PCT/IB00/00530</p> <p>(22) International Filing Date: 26 April 2000 (26.04.00)</p> <p>(30) Priority Data: <input checked="" type="checkbox"/> 99/3006 29 April 1999 (29.04.99) ZA</p> <p>(71)(72) Applicant and Inventor: LAMB, Peter, James, Brian [ZA/ZA]; 12 Clifford Avenue, 1675 Irene (ZA).</p> <p>(74) Agent: VAN DER WALT, Louis, Stephanus; Adams &amp; Adams Pretoria Office, Adams &amp; Adams Place, 1140 Prospect Street, Hatfield, P.O. Box 1014, 0001 Pretoria (ZA).</p>	<p>(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>	

(54) Title: DEVICE FOR DEPOSITING A NON-FLOWABLE OBJECT OR A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY



## (57) Abstract

A device (100) for depositing a non-flowable object or a non-flowable medicament in a body cavity includes an elongate body (12) which includes an elongate barrel (14) with a passage (18), configured to receive a non-flowable object or medicament, extending through the body (12). The passage (18) has an outlet (22) at a free end of the barrel (14), a portion of the passage (18) being curved. The device (10) also includes an ejector or plunger (30) which can be displaced along the passage (18) to push a non-flowable object or medicament received in the passage (18) out of the passage (18) through the outlet (22) thereof.

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

**DEVICE FOR DEPOSITING A NON-FLOWABLE OBJECT OR A NON-  
FLOWABLE MEDICAMENT IN A BODY CAVITY**

THIS INVENTION relates to a device for depositing a non-flowable object or a non-flowable medicament in a body cavity.

5                Various conventional devices for depositing a non-flowable medicament or object, such as a tablet in body cavities, such as the vagina and rectum, exist. Typically, these conventional devices comprises a blunt, straight, hollow tube or barrel into which a plunger or piston or ejector can be inserted from one end, with a medicament or object chamber being provided at an  
10                opposed end. All of the conventional devices suffer from at least some of the following problems:

                 The conventional device is of a hard and non-pliable material so there is no bend or give during insertion of the device into a vagina. This rigidity makes vaginal insertion more difficult and painful. Often women do not know  
15                that the vagina is angled upwards from its opening and that it is not horizontal. After inserting a leading end of the conventional device through the vaginal opening in the horizontal direction, the leading end collides with the back wall of the vagina, which is painful and causes the user to think that the device has  
20                reached the limit of the vagina. The user then deposits the medicament or object at a too shallow depth in the vagina. No stop guard is provided to limit the depth of insertion of the conventional devices into the vagina. If the device is

inserted to the full depth of the vagina and collides with the vaginal vault, considerable pain is caused. This lack of depth control is particularly hazardous in the case of a pregnant woman. Some conventional devices have leading ends which flare outwards which make them even more difficult to insert into a vagina. Conventional devices can only comfortably be inserted into a vagina when the woman is lying on her back with her knees flexed. It is difficult to insert conventional devices which are often difficult to grip and difficult to control when being inserted into a vagina.

It is an object of this invention to provide means which alleviate at least some of these problems.

According to a first aspect of the invention, there is provided a device for depositing a non-flowable object or a non-flowable medicament in a body cavity, the device including

an elongate body which includes an elongate barrel with a passage, configured to receive a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel, a portion of the passage being curved; and

an ejector or plunger which can be displaced along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof.

A barrel may be penile-shaped at least in cross section.

According to a second aspect of the invention, there is provided a device for depositing a non-flowable object or a non-flowable medicament in a body cavity, the device including

an elongate body which includes an elongate barrel with a passage, configured to receive a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel, the barrel being penile-shaped at least in cross section; and

an ejector or plunger which can be displaced along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof.

In this specification, the term "non-flowable medicament" is intended to include tablets, capsules, suppositories, pills, bougies, or the like.

A portion of the passage of the device according to the second aspect of the invention may be curved. The passage is typically round or circular in cross-section.

The passage may have an inlet remote from its outlet. The curved portion of the passage may render a centrally disposed longitudinal axis of the barrel and a centrally disposed axis through the inlet of the passage at an obtuse angle relative to each other. The obtuse angle may be between  $170^\circ$  and  $135^\circ$ . Preferably, the obtuse angle is between  $160^\circ$  and  $140^\circ$ , and most preferably between  $155^\circ$  and  $145^\circ$ , and is thus selected to correct for vaginal inclination.

The body of the device may include a gripping portion from which the barrel extends. The inlet of the passage may thus be in the gripping portion, which may be thickened compared to the barrel, thus also functioning in use as a stop formation, limiting the length of the body of the device which may be introduced into a body cavity.

The curved portion of the passage is typically located in the gripping portion of the body, so that the portion of the passage in the barrel is typically linear, allowing at least a portion of the barrel to be straight. Preferably, the entire barrel is straight, which is an advantage, since the human vagina is straight and not curved.

An outlet end portion of the barrel may have the general shape or may incorporate at least some of the design features of a glans penis. Thus, the



barrel may have a rounded point which flares back like the corona of a glans penis and which in use lifts the opposing vaginal walls apart when the barrel is inserted into a vagina by a wedging action. The roughly triangular cross-section of the barrel, similar to that of a penis, allows the smallest area of contact or friction with a posterior vaginal wall. Side walls of the barrel are thus in use angled away from lateral walls of the vagina, with a relatively broad superior wall of the barrel being stabilized by low pressure contact with the anterior vaginal wall.

The ejector or plunger may have a flexible rod, allowing the rod to bend to follow the curvature of the passage when it is displaced along the passage. The rod may be of a synthetic plastics or polymeric material, such as polypropylene or the like.

The passage may include a medicament or object chamber for receiving the non-flowable medicament or object. The chamber may be spaced from the outlet of the passage, allowing a part of the barrel, above the outlet, and a part of the barrel, below the outlet, to be displaced or forced towards each other when the barrel is being inserted into a body cavity, thus at least partially closing off the outlet whilst the barrel is being inserted into the body cavity and preventing the objet or medicament from scraping against or injuring body tissue material, such as the vaginal mucosa.

At least the barrel may be of a material having a Shore A hardness between 40 and 80, e.g. 70. Thus, the barrel may be of a synthetic plastics or polymeric material, such as silicone rubber, having a suitable hardness. The gripping portion may be of a thermoplastic material, with the barrel and the gripping portion being moulded or fused together. Instead, the barrel and the gripping portion may be fitted together by other means, such as glue or mechanical attachment means or combi moulding, thus advantageously allowing the gripping portion to be of a thermoplastic material which has a lower maximum working temperature than the moulding temperature of the material

of which the barrel is formed, and which may thus be cheaper. In another embodiment of the invention, the gripping portion and the barrel may both be of the same synthetic or polymeric plastics material, e.g. silicone rubber, the body of the device thus being monolithic and integrally moulded. Instead, the body and the ejector or plunger may be manufactured from paper or paper pulp, rendering the device disposable. The material may be selected to be biodegradable or to allow the device to be flushed safely down a toilet.

The barrel may have a length of between 60mm and 100mm, e.g. 70mm and a maximum external diameter of between 10mm and 20mm, e.g. 17mm, when the device is intended for a non-flowable medicament.

The outlet of the passage may be in the form of a slit extending between opposed sides of the barrel and may be located on the longitudinal axis of the barrel.

The body may define gripping surfaces such that the body can be gripped between a thumb, and index finger and a middle finger of one hand of a user. The gripping surfaces may be arranged such that when the body is being held between the three fingers, with the middle finger and the index finger touching the body in respective areas and the body being orientated such that said areas are in the same horizontal plane, the barrel projects upwardly away from said horizontal plane at an angle of between  $45^{\circ}$  and  $10^{\circ}$ .

The passage may be shaped and dimensioned to receive a tampon. The barrel may thus include a longitudinally extending slit through which a string of the tampon received in the passage can protrude.

In one embodiment of the invention, the slit may extend from the outlet and may form a right angle at an end of a longitudinally extending portion thereof remote from the outlet to extend transversely across an upper surface

displaceable in flip top fashion. This allows insertion of a solid object such as a tampon into the barrel from above, without having to feed the solid object into the barrel through the outlet.

5 The ejector or plunger may include a thumb grip at a free end of its rod, the gripping portion of the body defining a recess for the thumb grip so that almost all of the ejector or plunger can be received inside the body of the device when the ejector or plunger is pushed as far into the passage as it can go.

The invention will now be described, by way of example, with reference to the accompanying diagrammatic drawings in which

10 Figure 1 is a sectioned side view of an embodiment of a device in accordance with the invention for depositing a non-flowable medicament in a body cavity;

Figure 2 is a top plan view of the device of Figure 1;

Figure 3 is a bottom plan view of the device of Figure 1;

15 Figure 4 is a front end view of the device of Figure 1;

Figure 5 is a rear end view of the device of Figure 1;

Figure 6 is a sectioned side view of another embodiment of a device in accordance with the invention for depositing a non-flowable medicament or a non-flowable object in a body cavity;

20 Figure 7 is a top plan view of the device of Figure 6;

Figure 8 is a bottom plan view of the device of Figure 6;

Figure 9 is a front end view of the device of Figure 6; and

Figure 10 is a rear end view of the device of Figure 6.

25 Referring to Figures 1 to 5 of the drawings, reference numeral 10 generally indicates an embodiment of a device in accordance with the invention for depositing a non-flowable medicament or object in a body cavity, such as a vagina. The device 10 includes an elongate monolithic body 12 which comprises

an elongate barrel 14 and a gripping portion 16 from which the barrel 14 extends.

5 The barrel 14 and the gripping portion 16 are integrally moulded from a synthetic plastics or polymeric material such as a silicone rubber and has a Shore A hardness of about 70. A passage 18 extends through the gripping portion 16 and the barrel 14. The passage 18 has an inlet 20 in the gripping portion 16 and an outlet 22 at a free end of the barrel 14, remote from the gripping portion 16. A portion of the passage 18 between the inlet and the outlet and located in the gripping portion 16, is curved in side view, as can be clearly seen in Figure 1 of the drawings. The passage 18 is round in cross-section.

10 The curved portion of the passage 18 between its inlet 20 and its outlet 22 renders a centrally disposed longitudinal axis 24 of the barrel 14 and a centrally disposed axis 26 through the inlet 20 of the passage 18, at an obtuse angle of 150° relative to each other (see Figure 1), and this angle thus matches the angle of inclination of the vagina of a standing woman relative to the horizontal.

15 The barrel 14 is generally penile shaped and is thus roughly triangular in cross-section, similar to the cross section of a penis. More accurately, a cross-sectional outline of the barrel 14 falls on the outline of a triangle. An outlet end portion 28 of the barrel 14, remote from the gripping portion 16, generally has the shape of a glans penis. A bottom surface of the end portion 28 has a sled-like curve in side view to inhibit abrasion of the posterior vaginal wall in use. The barrel 14 thus has a rounded point which flares back like the corona of a glans penis and which in use lifts and wedges the opposing vaginal walls apart when the barrel 14 is inserted into a vagina.

20 The outlet 22 of the passage 18 is in the form of a slit extending between opposed sides of the barrel 14 and is located in an upper half of the

outlet end portion 28, to avoid scraping vaginal exudate into the outlet 22 during insertion of the barrel 14 into a vagina in use.

5 The device 10 includes a piston or ejector or plunger 30 which can be displaced along the passage 18 and which includes a flexible rod 32 of polypropylene. The rod 32 is thus able to follow the curvature of the passage 18 when the plunger 30 is displaced along the passage 18. The plunger 30 includes an ergonometically designed thumb grip 34 at a free end of the flexible rod 32. As can be clearly seen in Figure 1 of the drawings, the gripping portion 16 of the body 12 defines a recess 36 for the thumb grip 34 so that almost all of the plunger 30 can be received inside the body 12 when the plunger 30 is pushed as far into the passage 18 as it can go.

10 The passage 18 includes or defines a medicament or object chamber 38 (see Figure 1) for receiving the non-flowable medicament or non-flowable object. The chamber 38 is spaced from the outlet 22 of the passage and is in the form of a widening of the passage 18 tailored to receive a tablet or capsule or tampon or the like.

15 Roughened and depressed gripping surfaces 40 are provided on an external top surface and an external bottom surface of the gripping portion 16 of the body 12.

20 The barrel 14 is approximately 70mm long and has a maximum external diameter of about 17mm.

25 The device 10 is particularly, though not necessarily exclusively suitable for depositing a non-flowable medicament, such as a tablet or capsule, in a vagina. In use, the ejector or plunger 30 is withdrawn from the passage 18 at least far enough so that it does not protrude into the chamber 38, as shown in Figure 1 of the drawings, and the non-flowable medicament is placed inside the medicament chamber by inserting it through the outlet 22. The barrel 14 is

then inserted into a body cavity, such as the vagina of a human female until the gripping portion 16 limits the part or length of the body 12 of the device 10 which can be introduced into the vagina. Thus, the gripping portion 16 also functions in use as a stop formation. The gripping portion 16 affords a large comfortable grip for the hand of the person inserting the barrel 14 into the vagina.

As will be appreciated, since the body 12 is of a silicone rubber and thus quite flexible, a part or upper lip 42 of the barrel 14, above the outlet 22, and a part or lower lip 44 of the barrel 14, below the outlet 22 are displaced or forced towards each other whilst the barrel 14 is being inserted into the vagina. Thus, the outlet 22 is closed off whilst the barrel 14 is being inserted into the vagina, inhibiting intrusion of vaginal exudate into the passage 18 through the outlet 22. The flexibility of the lips 42, 44 also allows for easy insertion of the non-flowable medicament into the chamber 38 and prevents abrasion or injury to the vaginal mucosa by a sharp-edged non-flowable medicament, e.g. a vaginal tablet.

By enlarging the barrel 14 and the chamber 38, the device 10 can also easily be adapted for use in inserting a tampon in a vagina. Typically, in such a case, the barrel 14 will include a longitudinally extending slit through which a string of the tampon can protrude.

When the barrel 14 is fully inserted into the vagina, the ejector or plunger 30 is pushed into the body 12 as far as it can go, forcing the non-flowable medicament or solid object out of the chamber 38, through the outlet 22, and thus depositing the non-flowable medicament or object in the vagina. The barrel 14 is then withdrawn from the vagina.

Referring to Figures 6 to 10 of the drawings, reference numeral 100 generally indicates another embodiment of a device in accordance with the invention for depositing a solid object, such as a non-flowable medicament or a

non-flowable object, in a body cavity, such as a vagina. The device 100 is similar to the device 10, and unless otherwise indicated, the same parts or features are indicated by the same reference numerals used in relation to the device 10.

5           The body 12 of the device 100 is of Krayton G 2705 material having a Shore A hardness of 55. The ejector or plunger 30 is of the same material.

10           Unlike the outlet 22 of the device 10, the outlet 22 of the device 100 is located on a central longitudinal axis of the barrel 14 (not shown). Also unlike the device 10, the gripping portion 16 of the body 12 of the device 100 does not define a recess which can accommodate the thumb grip 34. Instead, when the ejector or plunger 30 is inserted fully into the passage 18, the thumb grip 34 abuts an end of the body 12 remote from the outlet 22.

15           The device 100 has a semi-circular 0.5 mm deep groove 102 in the upper lip 42 of the barrel 14. This facilitates bending of the upper lip 42 towards the lower lip 44 during insertion of the barrel 14 into a vagina thereby to close the outlet 22 off whilst the barrel 14 is being inserted into the body cavity. The groove 102 also facilitates the passage of a solid non-flowable object from the chamber 38 out through the outlet 22, by allowing the upper lip  
20           42 to move away from the lower lip 44.

25           The device 100 is used in similar fashion to the device 10. It is to be appreciated that, when the body 16 is gripped between a thumb, an index finger and a middle finger of one hand of a user, with the thumb touching the upper gripping surface 40 and the index finger and middle finger touching the lower gripping surface 40, and with areas on the lower surface 40 touched by the middle finger and the index finger being orientated such that they are in the same horizontal plane, the barrel 14 projects upwardly away from the horizontal plane

at an angle of about 30 °. If a woman holds the device 100 such that said areas touched by the middle and index finger are in line at an angle of about 120 ° to the horizontal, which is a natural holding position, the barrel 14 projects upwardly at an angle of about 150 ° relative to the horizontal, which is the angle of inclination of the vagina of a standing woman relative to the horizontal, as hereinbefore mentioned.

The Applicant believes that the device 10, 100 as illustrated, and particularly when intended to deposit a non-flowable medicament such as a capsule or tablet, or a solid object such as a tampon, in a vagina, has the following advantages:

The length of the barrel 14 is not intimidating, but nonetheless provides effective depth of deposition of the non-flowable medicament or the object. The barrel 14 is of a relatively soft, elastic material which is less difficult and painful to insert than the barrel of conventional devices. The material is easier for the fingers to grip securely and the grippability of the device is further improved by the gripping surfaces 40. The generally triangular, penile-like cross-section of the barrel 14 (see Figure 4) is easier and more comfortable to insert into a vagina. Friction against the back vaginal wall is reduced.

The angular arrangement of the barrel 14 relative to the inlet 20 of the passage 18 promotes easier advancement of the barrel 14 up the vagina. There is a built-in correction for the direction or inclination of the vaginal cavity, which causes less damage and discomfort to the user. The barrel 14 can be inserted whilst the user is sitting or standing and the procedure is therefor much easier and more comfortable to accomplish physically and much less an affront to a female's dignity.

The glans penis-like outlet end portion 28 of the barrel 14 of the device 10 is easier and more comfortable to insert than the leading end portions of conventional devices. The shape and location of the outlet 22 of the barrel



14 provides for better hygiene and promotes comfort when the barrel 14 is inserted into the vagina, by eliminating any scraping effect on the back wall of the vagina.

5 The thickened gripping portion 16 ensures automatic depth control when the barrel 14 is inserted into a vagina.

The integrally moulded design of the gripping portion 16 and the barrel 14 provides the device 10, 100 with a degree of flexibility, which enhances comfort and ease when the barrel 14 is inserted into a vagina.

10 The gripping portion 16 provides a large comfortable handle for the device 10. It affords a secure grip and therefor better control of the device 10 during insertion of the barrel 14 into the vagina.

CLAIMS:

1. A device for depositing a non-flowable object or a non-flowable medicament in a body cavity, the device including

an elongate body which includes an elongate barrel with a passage, configured to receive a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel, a portion of the passage being curved; and

an ejector or plunger which can be displaced along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof.

2. A device as claimed in claim 1, in which the barrel is penile-shaped at least in cross section.

3. A device for depositing a non-flowable object or a non-flowable medicament in a body cavity, the device including

an elongate body which includes an elongate barrel with a passage, configured to receive a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel, the barrel being penile-shaped at least in cross section; and

an ejector or plunger which can be displaced along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof.

4. A device as claimed in claim 3, in which a portion of the passage is curved.

5. A device as claimed in claim 1 or claim 2 or claim 4, in which the passage has an inlet remote from its outlet and in which the curved portion of the passage renders a centrally disposed longitudinal axis of the barrel and a

centrally disposed axis through the inlet of the passage at an obtuse angle of between 170 ° and 135 ° relative to each other.

6. A device as claimed in claim 5, in which the obtuse angle is between 160 ° and 140 ° relative to each other.

5 7. A device as claimed in claim 5 or claim 6, in which the body of the device includes a gripping portion from which the barrel extends, the inlet of the passage being in the gripping portion, and the gripping portion being thickened compared to the barrel, the gripping portion thus also functioning in use as a stop formation, limiting the length of the body of the device which may be  
10 introduced into a body cavity.

8. A device as claimed in claim 7, in which the curved portion of the passage is located in the gripping portion of the body, and in which the entire barrel is straight.

15 9. A device as claimed in any one of the preceding claims, in which an outlet end portion of the barrel has the general shape, or incorporates at least some of the design features of a glans penis.

10. A device as claimed in any one of the preceding claims, in which the ejector or plunger includes a flexible rod, allowing the rod to bend.

20 11. A device as claimed in any one of the preceding claims, in which the passage includes a medicament or object chamber for receiving the non-flowable medicament or object.

25 12. A device as claimed in claim 11, in which the chamber is spaced from the outlet of the passage, allowing a part of the barrel, above the outlet, and a part of the barrel, below the outlet, to be displaced or forced towards each other when the barrel is being inserted into a body cavity, thus at least partially

closing off the outlet whilst the barrel is being inserted into the body cavity and preventing the object or medicament from scraping against or injuring body tissue material.

5 13. A device as claimed in any one of the preceding claims, in which the barrel includes a longitudinally extending slit through which a string of a tampon received in the passage can protrude, the passage being shaped and dimensioned to receive a tampon.

14. A device as claimed in any one of the preceding claims, in which at least the barrel is of a material having a Shore A hardness between 40 and 80.

10 15. A device as claimed in any one of the claims 1 to 14 inclusive, in which the body and the ejector or plunger are manufactured from paper or paper pulp, rendering the device disposable.

15 16. A device as claimed in any one of the preceding claims, in which the body defines gripping surfaces such that the body can be gripped between a thumb, an index finger and a middle finger of one hand of a user, the gripping surfaces being arranged such that when the body is being held between the three fingers, with the middle finger and the index finger rouching the body in respective areas and the body being orientated such that said areas are in the same horizontal plane, the barrel projects upwardly away from said horizontal  
20 plane at an angle of between 45 ° and 10 °.

17. A device as claimed in claim 1 or claim 3, substantially as herein described and illustrated.

18. A new device, substantially as herein described.

